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Pamela W. Barclay
 Director, Center for Hospital Services
 Maryland Health Care Commission
 4160 Patterson Avenue
 Baltimore, Maryland 21215

RE: Proposed Amendments to COMAR 10.24.17, Table A-1

Dear Ms. Barclay:

On behalf of the Johns Hopkins Health System ("JHHS") and its three member hospitals, I would like to offer the following comments regarding the proposed amendment to COMAR 10.24.17, Table A-1. These changes will result in the codification as Maryland regulation the primary percutaneous coronary intervention ("pPCI") door-to-balloon ("DTB") time guideline of 90 minutes or less for 75 percent of appropriate patients, proposed as part of the 2007 Focused Update of the American College of Cardiology/American Heart Association 2004 Guidelines for the Management of Patient with ST-Elevation Myocardial Infarction.

First, we fully support the goal of less than 90 minutes from first medical contact to balloon inflation for 75 percent of STEMI patients, and we strive to achieve this goal for every patient. Clearly, the Commission's intent is to adopt a national cardiology guideline into a regulatory requirement for pPCI programs, which will improve the overall quality of STEMI care.

Second, we would like to remind the Commission that only 40 percent of patients nationwide receive primary PCI in less than 90 minutes, and this has not changed in over a decade. While we applaud the Commission's intent to change this trend in Maryland, this sobering statistic underscores the significant challenges faced by individual hospitals and providers to achieve a DTB time of less than 90 minutes. As such, the Commission may want to consider a phased-in requirement in which the annual median DTB time is less than 90 minutes, with an ultimate goal of 75 percent of cases with a DTB time of 90 minutes.

Third, the Commission and its staff need to recognize that there are circumstances in which patient variables, rather than a pPCI program failure, lead to clinically appropriate delays in the provision of STEMI care. In other words, a prolonged DTB time does not always constitute bad or inappropriate patient care. The 2007 Update itself states:

It is important to note that the door-to-balloon goal is a systems goal that may not be possible to achieve for an individual patient because of patient variables (uncertainty about diagnosis, evaluation and treatment of other life-threatening conditions, obtaining informed consent, etc.) that delay the patient's arrival in the

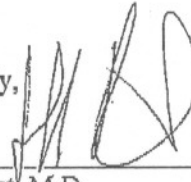
interventional cardiology laboratory or anatomical challenges (issues of arterial, coronary, or lesion access) that prolong the PCI procedure.

Fourth, the 75 percent threshold for cases that meet the 90 minute goal is arbitrary. It is entirely possible that a good PCI program may look "bad," in terms of DTB performance, simply because we serve a more complicated patient population, with more clinically appropriate delays, than other programs. The establishment of a new DTB goal without a mechanism for excluding patients with clinically appropriate delays sends a powerful message: doing things faster is more important than doing things the right way.

We believe there should be a mechanism to exclude patients with prolonged DTB times due to clinically or technically appropriate delays. There is existing precedent for such a mechanism; the Joint Commission (formerly JCAHO) allows hospitals to exclude such patients from their core measures analysis if they can document a clinically appropriate reason for patient delay. The MHCC should consider a similar mechanism for the pPCI waiver hospitals.

Thank you for providing us with this opportunity to comment on the proposed changes. If you have any questions, please do not hesitate to contact me at 410-550-2463. We very much appreciate your support and your dedication to the success of the pPCI programs of Hopkins Medicine.

Sincerely,



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